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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,856

12/04/2003

Manne Satyanarayana Reddy

BULK 3.0-034

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7590

12/05/2006

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EXAMINER

GRAZIER, NYEEMAH

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/729,856

Applicant(s)

REDDY ET AL.

Examiner

Nyeemah Grazier

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**  
Restriction Letter

**NOTE:** The Office Action/Restriction Letter mailed on or about May 9, 2006 has been vacated. The following Action/Restriction Letter will replace the previous Action.

**I. ACTION SUMMARY**

Claims 1-88 are currently pending in the instant application and are subject to the required restrictions and elections as described below.

**II. RESTRICTION**

Restriction to one of the following Inventions is required pursuant to 35 U.S.C. § 121, wherein an Invention is a set of patentable distinct inventions of a broad statutory category.

- I. Claims 1-7, 17-23, drawn to a crystalline product, classified in class 544, subclass 396 and class 514, subclass 255.04.
- II. Claims 8-12, drawn to a process of preparing a crystalline product, classified in class 544, subclass 396.
- III. Claims 13-16, drawn to a crystalline product by process, classified in class 544, subclass 396 and class 514, subclass 255.04.
- IV. Claims 24-28, process of preparing a crystalline product, classified in class 544, subclass 396.
- V. Claims 29-34, 87-88, drawn to a crystalline product by process, classified in class 544, subclass 396 and class 514, subclass 255.04.
- VI. Claims 35-48, 62-75, drawn to an amorphous form of a product, classified in class 544, subclass 396 and class 514, subclass 255.04.

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- VII. Claims 49-55, drawn to a process for the preparation of an amorphous product, classified in class 544, subclass 396.
- VIII. Claims 56-61, drawn to an amorphous product by process, classified in class 544, subclass 396 and class 514, subclass 255.04.
- IX. Claims 76-82, drawn to process for the preparation of an amorphous product, classified in class 544, subclass 396.
- X. Claims 83-86, drawn to an amorphous product by process, classified in class 544, subclass 396 and class 514, subclass 255.04.

*Rationale Establishing Patentable Distinctiveness Within Each Group*

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes or operation, different functions or different effects. See MPEP §§ 806.04, 808.01. In the instant case, the invention of group I is drawn to a crystalline product while the invention of group IV is drawn to an amorphous product.

Inventions II-III, IV-V, VII-VIII, and IX-X are related as product by process and process of preparing the product. However, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for preparing the product as claimed can be practiced with another materially different product or (2) the product as claimed can be made using a materially different process of using that product M.P.E.P. § 806.05. In the instant case, the process steps may be used to make materially different products.

Additionally, there are variable products of cetirizine (e.g. crystalline, amorphous, crystalline characterized by x-ray diffraction patterns). Also, there is no co-action among the various groups and a reference anticipating one group will not necessarily render another obvious.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

*Advisory of Rejoinder*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

*Telephone Inquiry*

A telephone call was made to Robert Franks on or about November 21, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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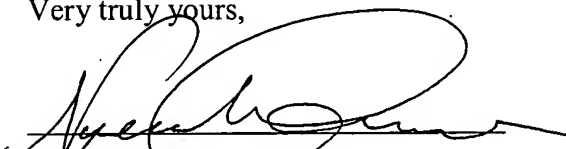
currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

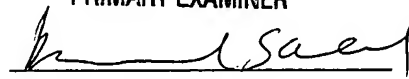
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>s</sup>Kane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

  
**Nyeemah Grazier, Esq.**  
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**PRIMARY EXAMINER**



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